11/2/2010

To: Scientific & Medical Accountability Standards Working Group (SWG)
Fr: CIRM
Re: Consistency of Australian Licensing Under the Research Involving Human Embryo Act 2002 with Title 17 California Code of Regulations Section 100010-100110

Background:

All hESC lines used in CIRM-funded research must comply with specific standards for acceptable derivation. CIRM recognizes as "acceptably derived" human embryonic stem cell lines created in accordance with the procedures and policies of six authorized authorities. These authorities are:

1. The U.S. National Institutes of Health
2. The United Kingdom Stem Cell Bank
3. The United Kingdom Human Fertilization and Embryology Authority
4. The Canadian Institutes of Health Research
5. The Japanese Ministry of Education, Culture, Sports, Science and Technology
6. The California Institute for Regenerative Medicine

Australia has a national licensing system promulgated pursuant to the Research Involving Human Embryos Act 2002. Under this act research involving human embryos can only be performed if authorized by the National Health and Medical Research Council through a specific research license. Human Research Ethics Committee approval is a prerequisite for every license application and any variation to an existing license. A license is only issued if the proposed research complies with the Ethical Guidelines on The Use of Assisted Reproductive Technology in Clinical Practice and Research. These guidelines include the following requirements:

- Informed Consent

The Licensing Committee must be satisfied that the research protocol includes proper consent from each person responsible for the embryo [gamete providers, their spouses, and the woman for whom the embryo was crated and her partner (if different from gamete provider)]. The consent process must be separated from clinical care and the guidelines require a "cooling-off" period before the consent becomes effective to allow the donor(s) to withdrawal. In practice the Human Research Ethics Committee has use a

two stage consent process. Stage 1 consent is for the use of donor embryos and stage 2 consent if for the use of any derived hESC lines. See table 1 for additional information regarding consent requirements.

- Payments and Expenses for Donors

The guidelines contain a prohibition on the commercial trading in human eggs, sperm or embryos. They also stipulate there should be no payments or other inducements for the donation of gametes, gonadal tissue or cells for research. The reimbursement of reasonable out-of-pocket expenses associated with the procedures is acceptable.

- Oversight

Human Research Ethics Committee approval is a prerequisite for every license application and any variation to an existing license. The committee will review the justification for the use of human embryos and place appropriate restrictions on the number that may be used for the specific license.

- Other Issues

Consistent with the CIRM regulations and international guidelines, the ethical guidelines:

- Prohibit reproductive cloning
- Developing a human embryo ex-vivo past 14 days

Table 1: NHMRC Consent & Disclosure Requirements Compared to CIRM Requirements

General Requirements CIRM Requirements	**NHMRC Requirement**
Consent from all gamete donors	Consent from all gamete donors and spouse or partner
No payments	No payments or other inducements for donations for research subject to the guidelines
Embryos will be destroyed in the derivation process	A full explanation of what will happen to each embryo is required

	Section 1 Consent Requirements: CIRM Requirements	**NHMRC Requirement**	**Comment**
a	Cells or cell products may be kept for many years	Disclose that cell lines may be kept for some years	
b	Disclose whether cells will be identifiable / recontact	Any links must be confidential	Donors are given the option of being recontacted if a clinically-relevant finding emerges
c	Cell lines may be used in future studies not now foreseeable	Disclose that donor will not be consulted about subsequent research involving hESC lines	
d	Cells or cell products may be genetically manipulated	General provision requiring researchers to "ensure that all persons are given information about the proposed research."	
e	Cells or cell products may be transplanted to humans	General provision requiring researchers to "ensure that all persons are given information about the proposed research."	For GMP compliant lines there would be discussion of screening and transplantation
f	Cells or cell products are not intended to provide direct medical benefit to donor	General provision requiring researchers to "ensure that all persons are given information about the proposed research."	
g	Donation is being made without restriction on the recipient of transplanted cells		
h	Consent nor refusal will affect the quality of any care to the donor	Research donation must be separated from clinical care.	
i	Results may have commercial value and donor has not legal interest	Embry donors should be informed that they will not receive financial or any other commercial benefit	